PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	19 MAR 2010
Applicant's or agent's file reference 578492004740	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/021437	19 January 2010	20 January 2009

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61M 31/00 (2010.01)
USPC - 604/508

Applicant GUIDED DELIVERY SYSTEMS INC.

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	02 March 2010	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (July 2009)

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/021437

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/021437

Box No. V **Reasoned statement under Rule *43bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-45	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-45	NO
Industrial applicability (IA)	Claims	1-45	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3 and 7-10 lack an inventive step under PCT Article 33(3) as being obvious over US 2008/0172035 A1 to Starksen et al. (henceforth Starksen'035) modified by Otten.

Regarding Claim 1, Starksen'035 discloses a method comprising: advancing a first catheter through a lumen of a second catheter (advance first delivery catheter through lumen of tunnel catheter 350, Fig. 3A); and advancing a portion of the first catheter through an opening in a wall portion or at a distal end of the second catheter (The tunnel catheter may have an opening positioned along its side wall, or otherwise positioned proximally of its-distal tip, and in some variations, the first delivery catheter is advanced through the opening, Para. [0010]); but fails to explicitly teach of advancement until the wall portion of the second catheter is positioned between a wall portion of the first catheter and a stop element of the first catheter, wherein the positioning of the wall portion of the second catheter between the wall portion and stop element of the first catheter prevents further advancement of the first catheter through the opening in the wall portion or at the distal end of the second catheter. Otten, however, teaches wherein a first catheter is advanced until the wall portion of the second catheter is positioned between a wall portion of the first catheter and a stop element (40) of the first catheter, wherein the positioning of the wall portion of the second catheter between the wall portion and stop element of the first catheter prevents further advancement of the first catheter through the opening in the wall portion or at the distal end of the second catheter (with stylet 22 only partially inserted as in FIGS. 1 and 4, lobes 26 are in the extended position. In this position the distal end 38 of inner tubular member 34 butts against a capture member 40, acting as a stop, Fig. 4. Capture member 40 is positioned near the distal end of the catheter and is secured to the inner surface of outer tubular member 32, Fig. 5 and Col. 19-25). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the internal stop mechanism of Otten with the disclosure of Starksen'035 to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 2, Starksen'035 modified by Otten discloses the method of Claim 1. Starksen'035 fails to explicitly teach wherein the stop element of the first catheter remains within the lumen of the second catheter while the portion of the first catheter is advanced through the opening in the wall portion or at the distal end of the second catheter. Otten, however, teaches wherein a stop element (40) of a first catheter remains within the lumen of the second catheter while the portion of the first catheter is advanced through the opening in the wall portion or at the distal end of a second catheter (with stylet 22 only partially inserted as in FIGS. 1 and 4, lobes 26 are in the extended position. In this position the distal end 38 of inner tubular member 34 butts against a capture member 40, acting as a stop, Fig. 4. Capture member 40 is positioned near the distal end of the catheter and is secured to the inner surface of outer tubular member 32, Fig. 5 and Col. 19-25). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the internal stop mechanism of Otten with the disclosure of Starksen'035 to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 3, Starksen'035 modified by Otten discloses the method of Claim 1. Starksen'035 further teaches wherein advancing the portion of the first catheter through the opening in the wall portion or at the distal end of the second catheter comprises pushing the portion of the first catheter through the opening with a pushing member (after delivery catheter 424 has been advanced through tunnel catheter 410, delivery catheter 424 is advanced through opening 416 in distal portion 411 of tunnel catheter 410, and is used to deploy anchor 426, Para. [0061]).

Regarding Claim 7, Starksen'035 modified by Otten discloses the method of Claim 1. Starksen'035 further teaches wherein the method comprises advancing the portion of the first catheter through the opening in the wall portion or at the distal end of the second catheter (advance first delivery catheter through lumen of tunnel catheter 350, Fig. 3A); but fails to explicitly teach of advancing until the wall portion of the second catheter is wedged between the wall portion and stop element of the first catheter. Otten, however, teaches of advancing until a wall portion of the second catheter is wedged between the wall portion and stop element (40) of the first catheter (inner tubular member 38 moves along with 22 until 48 resides within 46 of 40, Fig. 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the internal stop mechanism of Otten with the disclosure of Starksen'035 to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 8, Starksen'035 modified by Otten discloses the method of Claim 1. Starksen'035 further teaches wherein the method further comprises deploying an anchor from the first catheter after the first catheter has been advanced through the opening in the wall portion or at the distal end of the second catheter (after delivery catheter 424 has been advanced through tunnel catheter 410, delivery catheter 424 is advanced through opening 416 in distal portion 411 of tunnel catheter 410, and is used to deploy anchor 426, Para. [0061]).

Regarding Claim 9, Starksen'035 modified by Otten discloses the method of Claim 8. Starksen'035 further teaches wherein the method further comprises retrieving the anchor after it has been deployed (anchor retrieval via retrieval suture, Para. [0074]).

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
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Regarding Claim 10, Starksen'035 modified by Otten discloses the method of Claim 8. Starksen'035 further teaches wherein the method further comprises withdrawing the portion of the first catheter back into the lumen of the second catheter after the anchor has been deployed from the first catheter (withdrawing delivery catheter, Cl. 26).

Claims 4-6 lack an inventive step under PCT Article 33(3) as being obvious over US 2008/0172035 A1 to Starksen et al. (henceforth Starksen'035) modified by Otten and Starksen'380 et al. (henceforth Starksen'380).

Regarding Claim 4, Starksen'035 modified by Otten discloses the method of Claim 1, but fails to explicitly teach wherein the stop element comprises an elongated flap. Starksen'380, however, teaches wherein a stop element comprises an elongated flap (2816, Fig. 28). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the elongated flap of Starksen'380 with the disclosure of Starksen'035 to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 5, Starksen'035 modified by Otten and Starksen'380 discloses the method of Claim 4, but fails to explicitly teach wherein the elongated flap extends through an opening in the wall portion of the first catheter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the elongated flap of Starksen'380 to protrude through the opening of Starksen'035 in Claim 1 above, to provide an adjustable stop element, since rearranging parts of an invention only involves routine skill in the art.

Regarding Claim 6, Starksen'035 modified by Otten and Starksen'380 discloses the method of Claim 4, but fails to explicitly teach wherein the elongated flap curves away from the wall portion of the first catheter as the wall portion of the second catheter becomes positioned between the wall portion and stop element of the first catheter. Starksen'380, however, teaches wherein an elongated flap moves away from the wall portion of the first catheter as the wall portion of the second catheter becomes positioned between the wall portion and stop element of the first catheter (2816/2818/2820 spring up away from the wall of 2814, Fig. 28, when a restraining sheath exposes 2800, Para. [0028]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow an elongated flap to curve away from the wall portion of a first catheter as the wall portion of a second catheter becomes positioned between the wall portion and stop element of the first catheter, since a change in shape of an element involves only routine skill in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the self-opening elongated flap of Starksen'380 with the disclosure of Starksen'035 to aid in the placement and cinching of anchors during mitral valve repair.

Claims 11-18 lack an inventive step under PCT Article 33(3) as being obvious over Otten modified by US 2008/0177380 A1 to Starksen et al. (henceforth Starksen'380) and US 2008/0172035 A1 to Starksen et al. (henceforth Starksen'035).

Regarding Claim 11, Otten discloses a catheter comprising: a tubular elongated member defining a proximal portion, a distal portion, and a lumen therethrough (2, Fig. 1); and a first stop element, wherein a first portion of the first stop element is disposed within the lumen of the tubular elongated member (inner surface of 26, Figs. 2&4); but fails to explicitly teach of a first stop element comprising an elongated flap, and a second portion of the first stop element extends through an opening in a wall portion of the tubular elongated member. Starksen'380, however, teaches of a stop element comprising an elongated flap (2816, Fig. 28). In addition, Starksen'035 teaches of an opening in a wall portion of the tubular elongated member (The tunnel catheter may have an opening positioned along its side wall, or otherwise positioned proximally of its-distal tip, and in some variations, the first delivery catheter is advanced through the opening, Para. [0010]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the elongated flap of Starksen'380 to protrude through the opening of Starksen'035, to provide an adjustable stop element, since rearranging parts of an invention only involves routine skill in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the elongated flap of Starksen'380 and the sidewall opening of Starksen'035 with the disclosure of Otten to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 12, Otten modified by Starksen'380 and Starksen'035 discloses the catheter of Claim 11. Otten fails to explicitly teach wherein the catheter further comprises an anchor disposed within the lumen of the tubular elongated member. Starksen'380, however, teaches of an anchor disposed within the lumen of the tubular elongated member (anchor 2314 is delivered via outer sheath 2306, Figs. 23A&B and Para. [0050]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the anchor delivery approach of Starksen'380 with the disclosure of Otten to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 13, Otten modified by Starksen'380 and Starksen'035 discloses the catheter of Claim 12. Otten fails to explicitly teach wherein the catheter further comprises a coupling member coupled to the anchor. Starksen'380, however, teaches wherein the catheter further comprises a coupling member coupled to the anchor (2608 coupled to 2602, Fig. 26B). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the tether of Starksen'380 with the disclosure of Otten to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 14, Otten modified by Starksen'380 and Starksen'035 discloses the catheter of Claim 11. Otten further teaches wherein the catheter further comprises a second stop element disposed within the lumen of the tubular elongated member (with stylet 22 only partially inserted as in FIGS. 1 and 4, lobes 26 are in the extended position. In this position the distal end 38 of inner tubular member 34 butts against a capture member 40, acting as a stop, Fig. 4. Capture member 40 is positioned near the distal end of the catheter and is secured to the inner surface of outer tubular member 32, Fig. 5 and Col. 19-25).

Supplemental Box

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Regarding Claim 15, Otten modified by Starksen'380 and Starksen'035 discloses the catheter of Claim 14. Otten further teaches wherein the second stop element comprises a tubular member (capture member 40, acting as a stop, Fig. 4).

Regarding Claim 16, Otten modified by Starksen'380 and Starksen'035 discloses the catheter of Claim 14. Otten further teaches wherein the second stop element is coupled to or integral with the first stop element (26 is coupled to 40 via inner tubular member 34, Fig. 4).

Regarding Claim 17, Otten modified by Starksen'380 and Starksen'035 discloses the catheter of Claim 14. Otten further teaches wherein the second stop element (40) is separate from the first stop element (26, Fig. 4).

Regarding Claim 18, Otten modified by Starksen'380 and Starksen'035 discloses the catheter of Claim 14. Otten further teaches wherein the catheter further comprises a pushing member (22) including a distal portion comprising a first region having a first cross-sectional diameter (48) and a second region having a second cross-sectional diameter that is smaller than the first cross-sectional diameter (shaft of 22, Fig. 4).

Claims 19-23 lack an inventive step under PCT Article 33(3) as being obvious over Otten modified by US 2008/0177380 A1 to Starksen et al. (henceforth Starksen'380), US 2008/0172035 A1 to Starksen et al. (henceforth Starksen'035) and To et al. (henceforth To).

Regarding Claim 19, Otten modified by Starksen'380 and Starksen'035 discloses the catheter of Claim 11, but fails to explicitly teach wherein the tubular elongated member comprises a first region defining a first plane, a second region defining a second plane, and a curve between the first and second regions. To, however, teaches wherein a tubular elongated member comprises a first region defining a first plane (102, Fig. 1), a second region defining a second plane (distal end of shaft 102 at 104, Fig. 1), and a curve between the first and second regions (114). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the curved anchor delivery shaft of To with the disclosure of Otten to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 20, Otten modified by Starksen'380, Starksen'035 and To discloses the catheter of Claim 19, but fails to explicitly teach wherein the first and second planes have an angle of about 10 degrees to about 90 degrees therebetween. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 10 degrees to about 90 degrees therebetween, to more easily conform to the geometry of the atrio-ventricular valve, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 21, Otten modified by Starksen'380, Starksen'035 and To discloses the catheter of Claim 20, but fails to explicitly teach wherein the first and second planes have an angle of about 20 degrees to about 80 degrees therebetween. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 20 degrees to about 80 degrees therebetween, to more easily conform to the geometry of the atrio-ventricular valve, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 22, Otten modified by Starksen'380, Starksen'035 and To discloses the catheter of Claim 21, but fails to explicitly teach wherein the first and second planes have an angle of about 50 degrees to about 70 degrees therebetween. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 50 degrees to about 70 degrees therebetween, to more easily conform to the geometry of the atrio-ventricular valve, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 23, Otten modified by Starksen'380, Starksen'035 and To discloses the catheter of Claim 22, but fails to explicitly teach wherein the first and second planes have an angle of about 60 degrees. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 60 degrees, to more easily conform to the geometry of the atrio-ventricular valve, since discovering the optimum value of a result effective variable involves only routine skill in the art.

Supplemental Box

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Claims 24-26 lack an inventive step under PCT Article 33(3) as being obvious over US 2008/0177380 A1 to Starksen et al. (henceforth Starksen'380) modified by Otten.

Regarding Claim 24, Starksen'380 discloses a method for deploying an anchor into tissue of a subject comprising: advancing a distal portion of a pushing member (pusher referred to in Para. [0049]) disposed within a lumen of a first catheter (Figs. 4-5); an anchor (hooks 2314, Fig. 23B); and advancing the distal portion of the pushing member against the anchor to deploy the anchor from the lumen of the first catheter (Para. [0049]) and into tissue of a subject (Figs. 23A&B); but fails to explicitly teach of advancing the distal portion of a pushing member into a tubular stop element; wherein the tubular stop element is coupled to an anchor; and wherein the distal portion of the pushing member and the tubular stop element are configured to limit further distal advancement of the pushing member once the distal portion of the pushing member has been advanced into the tubular stop element. Otten, however, teaches of advancing the distal portion of a pushing member (22/48) into a tubular stop element (40, Fig. 4); and wherein the distal portion of the pushing member and the tubular stop element are configured to limit further distal advancement of the pushing member once the distal portion of the pushing member has been advanced into the tubular stop element (with stylet 22 only partially inserted as in FIGS. 1 and 4, lobes 26 are in the extended position. In this position the distal end 38 of inner tubular member 34 butts against a capture member 40, acting as a stop, Fig. 4. Capture member 40 is positioned near the distal end of the catheter and is secured to the inner surface of outer tubular member 32, Fig. 5 and Col. 19-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow an anchor to be coupled to a tubular stop element, to enable simultaneous delivery to a specific location within the body via a catheter, since the use of a one piece construction instead of the structure disclosed in Otten would have required only routine skill in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the internal stop mechanism of Otten with the disclosure of Starksen'380 to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 25, Starksen'380 modified by Otten discloses the method of Claim 24. Starksen'380 further teaches wherein the method further comprises using the pushing member (2302/2304) to decouple the anchor (2312/2314) from the tubular stop element (as evident in Figs. 23A&B).

Regarding Claim 26, Starksen'380 modified by Otten discloses the method of Claim 24. Starksen'380 fails to explicitly teach wherein the distal portion of the pushing member comprises a first region having a first cross-sectional diameter and a second region having a second cross-sectional diameter that is smaller than the first cross-sectional diameter. Otten, however, teaches wherein a catheter comprises a pushing member (22) including a distal portion comprising a first region having a first cross-sectional diameter (48) and a second region having a second cross-sectional diameter that is smaller than the first cross-sectional diameter (shaft of 22, Fig. 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the variable diameter pusher of Otten with the disclosure of Starksen'380 to aid in the placement and cinching of anchors during mitral valve repair.

Claims 27-30 lack an inventive step under PCT Article 33(3) as being obvious over US 2008/0177380 A1 to Starksen et al. (henceforth Starksen'380) modified by Otten and US 2008/0172035 A1 to Starksen et al. (henceforth Starksen'035).

Regarding Claim 27, Starksen'380 modified by Otten discloses the method of Claim 24. Starksen'380 fails to explicitly teach wherein the method further comprises advancing the first catheter through an opening in a wall portion or at a distal end of a second catheter. Starksen'035, however, teaches of advancing a first catheter through an opening in a wall portion (The tunnel catheter may have an opening positioned along its side wall, or otherwise positioned proximally of its-distal tip, and in some variations, the first delivery catheter is advanced through the opening, Para. [0010]) or at a distal end of a second catheter (after delivery catheter 424 has been advanced through tunnel catheter 410, delivery catheter 424 is advanced through opening 416 in distal portion 411 of tunnel catheter 410, and is used to deploy anchor 426, Para. [0061]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the sidewall opening of Starksen'035 with the disclosure of Starksen'380 to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 28, Starksen'380 modified by Otten and Starksen'035 discloses the method of Claim 27. Starksen'380 fails to explicitly teach wherein the tubular stop element is coupled to or integral with a second stop element. Otten, however,teaches wherein a tubular stop element (26, Figs. 2&4) is coupled to or integral with a second stop element (26 is coupled to 40 via inner tubular member 34, Fig. 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the dual stop element approach of Otten with the disclosure of Starksen'380 to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 29, Starksen'380 modified by Otten and Starksen'035 discloses the method of Claim 28. Starksen'380 fails to explicitly teach wherein the advancement of the first catheter through the opening in the wall portion or at a distal end of the second catheter stops when the wall portion of the second catheter becomes positioned between the second stop element and a wall portion of the first catheter. Otten, however, teaches wherein advancement of a first element through a second element stops when the wall portion of the second element becomes positioned between the second stop element (40) and a wall portion of the first element (inner tubular member 38 moves along with 22 until 48 resides within 46 of 40, Fig. 4). In addition, Starksen'035 teaches of advancement of a first catheter through the lumen of a second catheter (advance first delivery catheter through lumen of tunnel catheter 350, Fig. 3A, and wherein the tunnel catheter may have an opening positioned along its side wall, or otherwise positioned proximally of its-distal tip, and in some variations, the first delivery catheter is advanced through the opening, Para. [0010]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the dual stop element approach of Otten and the telescoping catheter approach of Starksen'035 with the disclosure of Starksen'380 to aid in placement and cinching of anchors during mitral valve repair.

Regarding Claim 30, Starksen'380 modified by Otten and Starksen'035 discloses the method of Claim 28. Starksen'380 further teaches wherein the second stop element comprises an elongated flap extending from the tubular stop element (2816, Fig. 28).

Supplemental Box

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Claims 31-36 and 38 lack an inventive step under PCT Article 33(3) as being obvious over Otten modified by US 2008/0177380 A1 to Starksen et al. (henceforth Starksen'380).

Regarding Claim 31, Otten discloses an anchor deployment device comprising: a catheter defining a lumen for housing an anchor therein (2, Fig. 1); a pushing member at least partially disposed within the lumen (22/48, Fig. 4); and a tubular stop element disposed within the lumen (the distal end 38 of inner tubular member 34 butts against a capture member 40, acting as a stop, Fig. 4), wherein the pushing member and the tubular stop element are configured such that when the pushing member is advanced into the tubular stop element, the tubular stop element limits further distal advancement of the pushing member (with stylet 22 only partially inserted as in FIGS. 1 and 4, lobes 26 are in the extended position. In this position the distal end 38 of inner tubular member 34 butts against a capture member 40, acting as a stop, Fig. 4. Capture member 40 is positioned near the distal end of the catheter and is secured to the inner surface of outer tubular member 32, Fig. 5 and Col. 19-25); but fails to explicitly teach of a catheter defining a lumen for housing an anchor therein. Starksen'380, however, teaches of an anchor disposed within the lumen of the tubular elongated member (anchor 2314 is delivered via outer sheath 2306, Figs. 23A&B and Para. [0050]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the anchor delivery approach of Starksen'380 with the disclosure of Otten to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 32, Otten modified by Starksen'380 discloses the anchor deployment device of Claim 31. Otten fails to explicitly teach wherein the device further comprises an anchor disposed within the lumen of the catheter. Starksen'380, however, teaches of an anchor disposed within the lumen of the tubular elongated member (anchor 2314 is delivered via outer sheath 2306, Figs. 23A&B and Para. [0050]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the anchor delivery approach of Starksen'380 with the disclosure of Otten to aid in the placement and cinching of anchors during mitral valve repair.

Regarding Claim 33, Otten modified by Starksen'380 discloses the anchor deployment device of Claim 32, but fails to explicitly teach wherein the anchor is coupled to the tubular stop element. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow an anchor to be coupled to a tubular stop element, to enable simultaneous delivery to a specific location within the body via a catheter, since the use of a one piece construction instead of the structure disclosed in [the prior art] would have required only routine skill in the art.

Regarding Claim 34, Otten modified by Starksen'380 discloses the device of Claim 31. Otten further teaches wherein the pushing member (22) comprises a distal portion comprising a first region having a first cross-sectional diameter (48) and a second region having a second cross-sectional diameter that is smaller than the first cross-sectional diameter (shaft of 22, Fig. 4).

Regarding Claim 35, Otten modified by Starksen'380 discloses the anchor deployment device of Claim 34, but fails to explicitly teach wherein the distal portion of the pushing member is tapered. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the distal portion of a pushing member to be tapered rather than round as per Otten in Fig. 4, to increase the compactness of a device, since a change in shape of an element involves only routine skill in the art.

Regarding Claim 36, Otten modified by Starksen'380 discloses the device of Claim 31. Otten further teaches wherein the device further comprises a second stop element (26, Figs. 2&4) that is coupled to or integral with the tubular stop element (26 is coupled to 40 via inner tubular member 34, Fig. 4).

Regarding Claim 38, Otten modified by Starksen'380 discloses the anchor deployment device of Claim 36. Otten fails to explicitly teach wherein the second stop element is in the form of an elongated flap extending from the tubular stop element. Starksen'380, however, teaches wherein a stop element comprises an elongated flap (2816, Fig. 28). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the elongated flap of Starksen'380 with the disclosure of Otten to aid in the placement and cinching of anchors during mitral valve repair.

Claim 37 lacks an inventive step under PCT Article 33(3) as being obvious over Otten modified by US 2008/0177380 A1 to Starksen et al. (henceforth Starksen'380) and US 2008/0172035 A1 to Starksen et al. (henceforth Starksen'035).

Regarding Claim 37, Otten modified by Starksen'380 discloses the anchor deployment device of Claim 36, but fails to explicitly teach wherein the second stop element extends through an opening in a wall portion of the catheter. Starksen'035, however, teaches of an opening in a wall portion of a catheter (The tunnel catheter may have an opening positioned along its side wall, or otherwise positioned proximally of its-distal tip, and in some variations, the first delivery catheter is advanced through the opening, Para. [0010]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the stop member of Otten to protrude through the opening of Starksen'035, to provide an adjustable stop element, since rearranging parts of an invention only involves routine skill in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the sidewall opening of Starksen'035 with the disclosure of Otten to aid in the placement and cinching of anchors during mitral valve repair.

Claims 39-45 lack an inventive step under PCT Article 33(3) as being obvious over Otten modified by US 2008/0177380 A1 to Starksen et al. (henceforth Starksen'380) and To et al. (henceforth To).

Regarding Claim 39, Otten modified by Starksen'380 discloses the device of Claim 31, but fails to explicitly teach wherein the catheter comprises an elongated member comprising a first region defining a first plane, a second region defining a second plane, and a curve between the first and second regions. To, however, teaches wherein a tubular elongated member comprises a first region defining a first plane (102, Fig. 1), a second region defining a second plane (distal end of shaft 102 at 104, Fig. 1), and a curve between the first and second regions (114). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the curved anchor delivery shaft of To with the disclosure of Otten to aid in the placement and cinching of anchors during mitral valve repair.

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding Claim 40, Otten modified by Starksen'380 and To discloses the device of Claim 39, but fails to explicitly teach wherein the first and second planes have an angle of about 10 degrees to about 90 degrees therebetween. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 10 degrees to about 90 degrees therebetween, to more easily conform to the geometry of the atrio-ventricular valve, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 41, Otten modified by Starksen'380 and To discloses the device of Claim 40, but fails to explicitly teach wherein the first and second planes have an angle of about 20 degrees to about 80 degrees therebetween. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 20 degrees to about 80 degrees therebetween, to more easily conform to the geometry of the atrio-ventricular valve, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 42, Otten modified by Starksen'380 and To discloses the device of Claim 41, but fails to explicitly teach wherein the first and second planes have an angle of about 50 degrees to about 70 degrees therebetween . It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 50 degrees to about 70 degrees therebetween, to more easily conform to the geometry of the atrio-ventricular valve, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 43, Otten modified by Starksen'380 and To discloses the device of Claim 42, but fails to explicitly teach wherein the first and second planes have an angle of about 60 degrees . It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 60 degrees, to more easily conform to the geometry of the atrio-ventricular valve, since discovering the optimum value of a result effective variable involves only routine skill in the art.

Regarding Claim 44, Otten modified by Starksen'380 and To discloses the device of Claim 41, but fails to explicitly teach wherein the first and second planes have an angle of about 40 degrees to about 60 degrees therebetween. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 40 degrees to about 60 degrees therebetween, to more easily conform to the geometry of the atrio-ventricular valve, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 45, Otten modified by Starksen'380 and To discloses the device of Claim 44, but fails to explicitly teach wherein the first and second planes have an angle of about 50 degrees. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the angle between first and second planes to be about 50 degrees, to more easily conform to the geometry of the atrio-ventricular valve, since discovering the optimum value of a result effective variable involves only routine skill in the art.

Claims 1-45 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.